Board meeting

13 December 2023

Update on development, alignment and implementation of changes to NICE methods and processes

Purpose of paper

For information and approval

Board action required

The Board is asked to:

* Approve the Interim methods and process statement for incorporating and integrating NICE technology appraisals into guideline topic areas (Appendix D) to proceed to public consultation and delegate authority to the NICE Guidance Executive to approve the final version following consultation.
* Note the progress in other areas of the paper and provide a steer to inform further work.

Board sponsors

* Nick Crabb, Interim Director of Science, Evidence and Analytics
* Jonathan Benger, CBE, Chief Medical Officer and Interim Director, Centre for Guidelines
* Mark Chapman, Interim Director of Medical Technology Evaluation
* Helen Knight, Director of Medicines Evaluation

Update on development, alignment and implementation of changes to NICE methods and processes

1. NICE is transforming to become more relevant (by focusing on what matters most), more timely and useable and more impactful (by constantly learning from data and implementation).
2. A rolling programme of methods work underpins this transformation:
   * + Improving relevance through ensuring our new methods are working well, that we update methods through modular updates and consider flexibilities where relevant.
     + Improving timeliness through the proportionate approach to Technology Appraisals.
     + Improving usability through incorporation and integration of Technology Appraisal recommendations in guidelines.
3. Key progress and findings in each area are outlined below, with more information in the appendices.

Improving relevance

First year of implementation of the updated CHTE manual

1. Early experience following the implementation of the above manual was presented at the March 2023 Board meeting. This update reflects that the new manual has now been applied in committee meetings for a full year.
2. The manual has generally been well received. We have conducted quarterly reviews to monitor implementation, including areas such as where the severity modifier has been used, the use of real-world data in submissions and the use of additional flexibilities.
3. The severity modifier has been applied in multiple topics, both cancer and non-cancer. Severity weightings of both 1.7 and 1.2 have been applied. Wider use of the 1.2 severity weighting had been anticipated and this will be the subject of a review in 2024/25.
4. The use of real-world evidence is progressing well, with committees accepting it as primary or supportive evidence in several topics. There is also evidence of a trend towards increasing use of real-world evidence in company submissions and acceptance by committees.
5. The updated manual allows for committees to use additional flexibilities in some circumstances. Such flexibilities have been applied over multiple topics where there were significant challenges to evidence generation, where the technology addressed health inequalities, where there was high unmet need or where the committee considered that there were significant benefits beyond those reflected in the health economic model.
6. Further information is shown in Appendix A.

Modular updates

1. The intended approach to updating NICE manuals is to undertake reviews and updates that are limited to specific subject areas rather than periodic reviews of the entire manuals.
2. The first modular update of the CHTE Manual completed concerned the implementation of updates from the proportionate approach to technology appraisals (PATT) initiative. The update was published following a public consultation and included changes to the handling of confidential information, the cost comparison process and streamlined decision making.
3. The Guidelines Manual was also updated following a public consultation and included changes to the sections on scoping, searching for evidence, writing the guideline recommendations, finalising the guideline recommendations and support for putting the guideline recommendations into practice.
4. A NICE-wide framework for prioritising and delivering modular updates is under development and will be completed in Spring 2024
5. Further information is shown in Appendix B.

Use of existing flexibilities to adopt a broader perspective

1. In December 2022, the Board approved recommendations to strengthen internal processes within NICE to identify topics where wider costs and benefits, beyond those accruing to health and social care, are relevant and should be included within the scope of a NICE evaluation. The Board also requested an update on where the flexibilities to adopt a broader perspective had been applied.
2. We reviewed all Highly Specialised Technologies (HST) guidance published or updated since December 2022.Out of 8 topics, 4 considered the impacts of the technologies outside of direct health benefits with the committee agreeing that wellbeing and educational impacts were relevant and including them in deliberations. For one technology (HST27), the company provided quantitative evidence on benefits of returning to work. The committee questioned the assumptions and decided to consider these impacts qualitatively through their deliberations.
3. We also identified 1 technology appraisal completed since the implementation of the updated manual where evidence on wider outcomes was included in the submission (TA922). However, the company’s analysis of productivity benefits was not considered by the committee because it was not detailed in the final topic scope.

Improving timeliness

New methods and process from PATT initiative

1. The first round of new methods and processes form the Proportionate Approach to Technology Appraisals (PATT) work resulted in a 17% reduction in time taken on average for Technology Appraisals in 2023/24 to date, with more streamlined topics being evaluated up to 50% faster.
2. The updated methods and processes were implemented through a modular update as outlined above.

PATT Pathways

1. One of the current PATT projects, PATT Pathways aims to develop and apply core economic models, spanning disease pathways, to allow the evaluation of multiple technologies using each core model. This has the potential for improved efficiency as well as supporting more consistent guidance.
2. There are 2 on-going pilots to develop core economic models in renal cell carcinoma and non-small cell lung cancer.
3. Given the wide-reaching and transformational potential of this work, additional engagement is needed. An update will be provided for the Board meeting in March 2024.

Improving Usability

1. Our major focus on improving the useability of NICE guidance has been preparing for incorporating and integrating technology appraisals in guideline topic areas.
2. Currently, NICE’s guidance is published according to the programme that developed the guidance; this means that our users must search in multiple places to find all our guidance about a given condition.
3. To provide a better experience for our end users, help increase the adoption of NICE guidance, and provide better outcomes for patients and better use of NHS resources, we have developed approaches to the incorporation and integration of technology appraisals in guidelines such that all relevant information on a topic, can be conveniently accessed through the guideline. Although starting with technology appraisals, the intention is to extend the approach to the incorporation of medical technologies and diagnostic guidance.
4. Further details on the approach and progress are available in Appendix C. An interim methods statement for Board approval prior to consultation is shown in Appendix D.

Board action required

1. The Board is asked to:
   * Approve the Interim methods and process statement for incorporating and integrating NICE technology appraisals into guideline topic areas (Appendix D) to proceed to public consultation and delegate authority to the NICE Guidance Executive to approve the final version following consultation.
   * Note the progress in other areas of the paper and provide a steer to inform further work.

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Appendices

Appendix A: First year of implementation of the updated CHTE manual

Appendix B: Modular Updates

Appendix C: Incorporating and integrating technology appraisals in guideline topic areas: Interim methods and processes

Appendix D: Interim methods and process statement for incorporating and integrating NICE technology appraisals into guideline topic areas

Appendices

Appendix A: First year of implementation of the updated CHTE manual

1. This appendix summarises methods implementation for medicines appraisal topics using the [new manual for technology evaluation](https://www.nice.org.uk/process/pmg36/chapter/introduction-to-health-technology-evaluation). It covers topics that have been to committee meetings between October 2022 and September 2023, thereby covering the first full year of committee meetings when the new manual has been implemented. Please note that some of these topics are ongoing; outcomes on topics where final guidance have not been published at the time of writing are still subject to change.

Summary statistics for topics using new methods

1. Of all topics that have been to at least 1 committee meeting by the end of September 2023, 57 topics used the new manual for technology evaluation. Of these, 31 have published final guidance, 21 are at draft guidance stage (4 of which are under appeal), and 5 are waiting for guidance to be confirmed.
2. Of all 52 topics at either published or draft guidance stage, there have been more positive recommendations (28) than negative recommendations (23), and 1 appraisal that included both positive and negative recommendations.
3. The company applied for a severity modifier in 13 of the topics. In 11 cases (including 3 non-cancer appraisals), the application for a severity modifier was accepted by the committee. In 2 topics where an application for a 1.7 QALY weighting for severity was not accepted, the committee accepted a 1.2 weighting instead.
4. Real-world evidence was accepted by committee as primary or supportive evidence in 18 topics.
5. Additional flexibilities were granted in 16 topics: 7 due to difficulties with evidence generation; 2 to acknowledge impacts on health inequalities; 5 due to uncaptured benefits; and 2 due to unmet need. All of the additional flexibilities granted led to increased acceptable ICER thresholds in principle.
6. Please note that the additional flexibilities described here differ from the wider effects mentioned in relation to adopting a broader perspective. The former refer to health benefits not captured using the reference case methods whereas the latter refers to effects beyond direct health benefits.

Reflections on the implementations of new methods

1. The implementation of the manual is going well. Applications for a severity weighting have been accepted in a number of topics, including 3 for non-cancer appraisals. Committees are comfortable discussing other flexibilities available in the manual such as where evidence generation may be more difficult, and are comfortable taking into account real-world evidence.
2. We have collected and responded to feedback from patient groups and industry on the new manual (Table 1).

Table 1: Summary of feedback on the new CHTE manual

|  |  |
| --- | --- |
| **Feedback** | **NICE response** |
| **Patients** | |
| Patients requested additional clarity on how exactly severity was calculated and applied, and how they can add value to discussions. | NICE ran a patient-focused webinar in October 2023, explaining the severity modifier and how/when patients can best get involved. Included an opportunity to send questions in advance, and ask questions during the meeting. |
| Patients flagged that one of the benefits originally posited of the severity modifier was that it was designed to capture a broader range of conditions than end-of-life, which was typically focussed primarily on cancers. However, cancers still appear most commonly with severity. | Cancers are one of the most common topics that NICE reviews, which may account for their high representation in severity. However we are seeing a number of non-cancer topics apply for the severity modifier, and have seen committee accept severity for 3 non-cancer topics. We will continue to monitor for trends over time. |
| Patients stated that moving away from end-of-life to severity is unfair for those medicines who would have qualified for the former but will not qualify for the latter. | The CHTE 2020 Methods Review found that there was no evidence that society values treatments at the end of life over other treatments. The severity modifier is therefore a fairer and broader modifier taking into account quality of life and length of life, which better reflects societal preferences. We are actively monitoring all topics that go to committee, recording and analysing information such as the number of topics where the severity modifier was applied. |
| Patients stated that although NICE regularly acknowledges the patient impact in guidance documents, the documents do not tend to explicitly link the patient input to committee decision making. | Committee’s final decision making is complex and based on multiple criteria, and so decisions depend on a range of factors, rather than ‘x input directly led to y decision’. However, we will reflect on whether more can be done to demonstrate patient impact. |
| **Industry** | |
| Industry gave reports of some delays in process steps, and variabilities in information sharing across different teams within NICE. | NICE agrees that there have been some instances of delays and inconsistencies in information sharing, and recognises that improvements need to be made. NICE considers this to be primarily related to recruitment issues, which have now been addressed. However, feedback has been passed along internally, and will be actively monitored to ensure this does not continue to happen. |
| Industry raised concerns around the levels of transparency during committee meetings, with some pivotal discussions seeming to occur in the private rather than public sessions of the meetings. | NICE have been monitoring all committee meetings to observe the implementation of the new manual. As part of our reflections on these observations, we will be reminding committee that key discussions must happen in the public part of the meeting. |
| Industry noted some variability in how committee meetings are run, including different styles of committee chairs, and differing levels of company participation | NICE will reflect on whether more can be done to ensure external stakeholders are given the right levels of participation in committee meetings. But committee chairs have the freedom to reflect on the specific circumstances for each topic, such as the amount of time left for discussion, and whether more discussion on a particular issue is warranted. |
| **NICE findings from observing committee** | |
| NICE considers that in general, committees exhibit a high degree of consistency in how they make decisions. | NICE recognises that as the decision making happens in the closed part 2 of the meeting, committees can improve the transparency of their decision making by minimising the amount of discussion that happens in part 2 of the meeting. |
| NICE noted occasions where companies did not implement committee requests. For example, committee members requesting analyses for the next meeting, but the company declining to explore these requests. | Companies should note that disagreeing with committee requests is always acceptable, but companies should still implement the requested analyses alongside any points of disagreement they have. Committees identify what analyses they would like to see to aid their decision making. When such analyses are not provided by the company this can hinder decision making. |

Actions taken in response to feedback

1. We have taken the following actions in response to feedback on the implementation of the manual:
   * Created and implemented a structured decision support guide, to ensure continued consistency in committee decision making
   * Conducted a webinar for patients, to outline the methodology for calculating and applying the severity weight and explain how best patients can add value to committee severity discussions
   * Outlined additional guidance on how severity should be implemented when carer quality of life is included in the model
   * Regularly observed committees to ensure the new manual is being implemented fairly and consistently
   * Set up working groups to assist with the operationalisation of the manual.

Appendix B: Modular Updates

What is a modular update?

1. A modular update is a review of the processes and/or methods informing NICE’s guidance, limited to specific subject areas (e.g. children’s quality of life). These specific areas can be reviewed and updated as required, without needing full reviews of entire manuals.

What progress has been made on modular updates so far?

1. A draft framework for modular updates was outlined at the March Board meeting in [this paper](https://www.nice.org.uk/Media/Default/Get-involved/Meetings-In-Public/Public-board-meetings/march-23-pbm-proposed-approach-for-modular-updates-for-the-manual-for-technology-evaluation.docx). Since then, NICE has:
   * Agreed that modular updates will cover both technology evaluations and guideline development. This is to build on and further support ongoing alignment work between the Centre for Health Technology Evaluation (CHTE) and the Centre for Guidelines (CfG).
   * Incorporated the first round of the PATT (proportionate approach to technology appraisals) updates into the CHTE manual as the first modular update. This update was published following a 4-week public consultation and included changes to the handling of confidential information, the cost comparison process, and streamlined decision making. A report was published summarising the consultation comments received and the NICE responses.
   * Set up a cross-NICE working group to update and operationalise the modular updates framework.
   * Considered the important balance between ensuring our processes and methods remain agile and responsive to the needs of the health and care system, while providing stability and reliability for our stakeholders. The frequency and timing of engagement and consultation activities will be coordinated to reflect this need for balance.
2. NICE aims to have the framework up and running by spring 2024.

Appendix C: Incorporating and integrating technology appraisals in guideline topic areas: Interim methods and processes

Aim

1. To outline the interim methods and processes for incorporating and integrating NICE technology appraisals into guideline topic areas; enabling NICE to meet its objective of delivering useful and useable advice.

Why we are incorporating and integrating technology appraisals into guideline topic areas

1. Currently, NICE’s guidance is published according to the programme that developed the guidance; this means that our users must search in multiple places to find all our guidance about a given condition.
2. To provide a better experience for our end users, help to increase the adoption of NICE guidance, and provide better outcomes for patients and better use of NHS resources, we have developed two approaches that will facilitate bringing together NICE guidance on a topic, including newly recommended technologies.

What is being proposed?

1. We have proposed initial aligned methods and processes across CHTE and CfG that will support the incorporation and integration of technology appraisals.

Incorporation of technology appraisals

1. Where there is newly published technology appraisal guidance within the scope of a NICE guideline topic area, the technology appraisal recommendation will be incorporated into the guideline topic area with no change to the meaning, intent or funding requirement. Where there are existing technology appraisal recommendations in a guideline topic area that is being updated, these will also be incorporated.

Integration of technology appraisals

1. Technology appraisals will be integrated by undertaking comparative analysis of all appropriate treatment options in that decision space. Integration will only be used in selected decision spaces and if the criteria set out in paragraph 10 of Appendix D are met.

Key differences in methods and processes and how they have been aligned

1. Technology appraisals and guidelines programmes have different remits and underpinning legislation, and as such their methods and processes have evolved to reflect this.
2. To facilitate incorporation and integration of technology appraisals into guideline topic areas, we have sought to align differences in methods and processes where appropriate, taking into account the principles set out in paragraph 7 of Appendix D
3. The proposed changes to the methods set out in the guidelines manual to allow technology appraisal integration are outlined in paragraphs 17 to 36 of Appendix D, and include methods for assessing VAT, quantitative decision modifiers, cost-effectiveness, appeals and others.

What are the risks and benefits of these changes?

1. The benefits and risks of these changes include:
   * Present all NICE guidance in one clear, cohesive care pathway, reflecting evidence of effectiveness and cost-effectiveness.
   * More effective presentation of guidance to enable better implementation, improved uptake of guidance and better outcomes for people using health and care services.
   * Aligning and innovating methods and processes across centres, where appropriate.
   * Potential risk of legal challenge on the proposed approach to integration.

Next steps

Consultation and publication of the interim statement

1. The methods set out here for public consultation outline the general principles guiding our approach to incorporation and integration of technology appraisals into guideline topic areas.
2. We will consider all responses from stakeholders to the consultation on the interim methods and process statement, amend if necessary and then the final interim statement will be published.

Implementation and roll out of methods and processes

1. Incorporation of technology appraisal guidance into guideline topic areas is already in progress.
2. Integration of technology appraisal guidance will be piloted in at least 2 guideline topic area updates during 2024/25 with a view to progressing to implementation across the wider programme on publication of the final methods statement.

Equalities

1. A cross-organisation group considered the potential equalities impact of implementing these methods and processes and is satisfied that the guidance complies with NICE's obligations under the equalities legislation. Issues that were considered during the development of these methods and processes are reported in the ‘Equality and Health inequality assessment’, which will be consulted on alongside the interim methods and process statement.

Appendix D: Interim methods and process statement for incorporating and integrating NICE technology appraisals into guideline topic areas

Introduction

1. NICE’s core purpose is to help practitioners and commissioners get the best care to patients, fast, while ensuring value for the taxpayer.  For more than 20 years, NICE, guided by the [NICE charter](https://www.nice.org.uk/about/who-we-are/our-charter) and [NICE principles](https://www.nice.org.uk/about/who-we-are/our-principles), has played a key role in using the best available evidence to develop recommendations that guide decisions in health, public health and social care.
2. To support the changing needs and objectives of all parts of the health and care system, [NICE is transforming](https://www.nice.org.uk/about/who-we-are/corporate-publications/the-nice-strategy-2021-to-2026) to ensure our guidance remains relevant, timely, useable and impactful. To achieve these aims, the methods and processes that underpin our guidance need to evolve.

Why we are incorporating and integrating technology appraisals into guideline topic areas

1. Currently, NICE’s guidance is published according to the programme which developed the guidance. This means that our end users must search in multiple places to find all our recommendations about a given condition and cannot easily access and understand the totality of NICE’s guidance about each topic.
2. To provide a better experience for our end users, help to increase the adoption of NICE guidance and provide better outcomes for patients and better use of NHS resources, we are proposing to develop two approaches that will facilitate bringing together NICE guidance on a topic:

1. Rapid incorporation of all newly published technology appraisal guidance into NICE guideline topic areas. Technology appraisal recommendations that are in the scope of a guideline will be incorporated within the guideline by presenting the technology appraisal recommendations unchanged in the guideline. No comparative assessment is undertaken for the intervention against other treatment options. The technology appraisal recommendation and its funding requirement (when applied for positive recommendations) remain in place. Incorporation will enable NICE to provide useful and useable guidance in a timely way. We will also explore incorporation of existing technology appraisal guidance as an option.
2. Integration of existing technology appraisal guidance into NICE guideline topic areas. Where there are multiple treatment options in a decision space and no clear rationale for guiding treatment decisions, technology appraisal recommendations that are within the scope of a guideline topic area will be considered for integration into guideline topic areas (see the section on [the](bookmark://_Criteria_and_triggers) [methods and processes for integrating technology appraisal recommendations into guideline topic areas)](bookmark://_Methods_and_processes).  Technology appraisals will be integrated by undertaking comparative analysis of all appropriate treatment options in that decision space. Integration will only be used in selected decision spaces and if the criteria set out in the section on [criteria and triggers for integration of technology appraisal recommendations into guideline topic areas](bookmark://_Criteria_and_triggers) are met. Integration will enable NICE to publish robust, comprehensive and up-to-date guideline recommendations that provide clarity for end users in areas with multiple treatment options, and reflect a clinical pathway based on assessment of clinical and cost effectiveness of all options.

Approach taken to developing methods and processes to incorporate and integrate technology appraisals into guideline topic areas

1. Development of methods and processes to support the incorporation and integration of technology appraisals into guideline topic areas has several stages:
2. In the first stage, the general principles guiding our approach to incorporation and integration of technology appraisals into guideline topic areas will be set out alongside the key changes to existing methods and processes.  This is the basis of this consultation document: the interim method and process statement.
3. We will consult on this interim methods and process statement. NICE will consider responses from stakeholders to the consultation on the interim methods and process statement, amend the interim statement where necessary, and publish a final version.
4. We will pilot these interim methods and processes in a number of updates of guideline topics. This stage will inform the development of more detailed methods and processes to support implementation of the approach to incorporate and integrate technical appraisals into guideline topic areas.
5. After piloting these interim methods and processes, final methods and processes for integration and incorporation of technology appraisal recommendations into guideline topic areas will be consulted on and published in NICE’s methods manuals.
6. The methods and processes for incorporation of technology appraisals and integration of technologies will broadly be in line with those set out in the [NICE guideline manual](https://www.nice.org.uk/process/pmg20/chapter/introduction) which builds on the [NICE principles](https://www.nice.org.uk/about/who-we-are/our-principles).  Where stated, we will also apply the relevant section of the NICE health technology evaluations manual.
7. NICE’s technology appraisals and guidelines programmes have different remits and as such their methods and processes have evolved to reflect this. To facilitate incorporation and integration of technology appraisals into guideline topic areas, NICE recognises the need for closer alignment of the methods and processes underpinning the development of guidance across the different guidance-producing centres. Where differences in approach exist (for example, use of decision-modifiers in the NICE health technology evaluations manual) we have sought to align where appropriate, taking into account the following:
8. Maintaining access to the right treatments for patients and clinicians;
9. Protecting the NHS budget;
10. Operational feasibility for NICE and our system partners;
11. Ensuring the approach is methodologically robust and appropriate

Incorporation process for positive and negative technology appraisals

1. Where there is newly published technology appraisal guidance within the scope of a NICE guideline topic area, the technology appraisal recommendation will be incorporated into the guideline topic area with no change to the meaning, intent or funding requirement (where applied). The incorporation process will be carried out within NICE and will consider any existing treatment options in the decision space, whether topic expert input is needed, and whether additional guideline recommendations are needed to ensure that the care pathway is clear in presenting all the appropriate treatment options.
2. Where existing technology appraisal recommendations are identified in the same decision-space, all relevant technology appraisal recommendations (existing and newly published) will be incorporated. The timelines for this process will be tested on the pilot topics and detail will be added when the finalised methods and processes are consulted on.

Integration of technology appraisals

Criteria and triggers for integration of technology appraisal recommendations into guideline topic areas

1. Technology appraisal recommendations will be considered eligible for integration into a guideline topic area if they fulfil the following criteria:
2. There are multiple treatment options, including at least one technology appraisal within a decision space, and,
3. There is no clear or pre-specified rationale for choosing one treatment option over another within that decision space, and
4. Integration would not normally happen sooner than 3 years from the publication of the technology appraisal to publication of the guideline recommendations into which it would be integrated.

Methods and processes for integrating technology appraisal recommendations into guideline topic areas.

1. Guideline topic areas in which technology appraisal recommendations will be integrated will broadly follow the methods and processes set out in the [developing NICE guidelines: the manual](https://www.nice.org.uk/process/pmg20/chapter/ensuring-that-published-guidelines-are-current-and-accurate). Where differences in approach between NICE centres exist (for example, use of decision-modifiers in the NICE health technology evaluations manual) we have sought to align where appropriate; these include:

Surveillance

1. NICE guideline recommendations are subject to surveillance processes set out in [developing NICE guidelines: the manual](https://www.nice.org.uk/process/pmg20/chapter/ensuring-that-published-guidelines-are-current-and-accurate). NICE technology appraisal guidance that has been incorporated or integrated into a guideline topic area will be subject to surveillance processes as set out in Appendix O of [developing NICE guidelines: the manual.](https://www.nice.org.uk/process/pmg20/chapter/ensuring-that-published-guidelines-are-current-and-accurate)

Scoping

1. Scoping is carried out in line with the methods and processes outlined in [developing NICE guidelines: the manual](https://www.nice.org.uk/process/pmg20/chapter/introduction). The scope, or hub page will set out where integration of technology appraisal recommendations will be undertaken.
2. We will ensure that all the stakeholder organisations that participated in the technology appraisal will be registered as stakeholders for the guideline. Consultees on the original technology appraisal will retain that status.

Identifying the evidence

1. In line with the [developing NICE guidelines: the manual](https://www.nice.org.uk/process/pmg20/chapter/introduction), the best available evidence will be used to inform technology appraisal integration decisions, which may include specific calls for evidence and the use of real-world data, as outlined in [developing NICE guidelines: the manual](https://www.nice.org.uk/process/pmg20/chapter/introduction) and the [NICE real-world evidence framework.](https://www.nice.org.uk/corporate/ecd9/chapter/overview" \t "_blank)
2. As part of the technology appraisal integration process, NICE will request consent from relevant parties to share the confidential data (including the economic model) that was previously submitted as part of the technology appraisal evaluation with development teams in Centre for Guidelines.

VAT

1. VAT will be excluded from the integration decision space, for technology appraisal and non-technology appraisal guidance, as described in the NICE health technology evaluations manual.
2. Users will have the ability to include and exclude VAT in the resource impact assessment tools that publish alongside the guidance.

Quantitative decision modifiers

1. To enable consistent decision making across NICE guidelines and technology appraisals the quantitative modifiers introduced by the Centre for Health Technology Evaluation (CHTE) for technology appraisal guidance will be considered within the guideline where there is a technology appraisal that will be integrated.
2. Where a technology has previously received guidance from the Technology Appraisal Programme, the guideline committee will consider the application of relevant quantitative modifiers. Where severity considerations apply, this is defined as in NICE health technology evaluations manual.
3. If quantitative decision modifiers were used in the technology appraisal guidance, the guideline committee will be mindful of the continued acceptability of a technology as an effective use of NHS resources, should the relevant quantitative modifiers no longer be applicable, and will specifically consider if health outcomes would be significantly reduced if a technology was removed as an option. In these circumstances, the committee may be able to make recommendations applying greater flexibility around the range of acceptable cost effectiveness estimates.

 Cost effectiveness

1. As outlined within the [NICE principles](https://www.nice.org.uk/about/who-we-are/our-principles), NICE considers value for money of interventions by assessing the incremental cost-effectiveness ratio (ICER). Interventions with an ICER of less than £20,000 per QALY gained are generally considered to be cost-effective. Decisions must consider the evidence underpinning an evaluation, population need and the 'opportunity cost' of recommending one intervention instead of another. NICE recommendations also take into account other factors beyond the evidence of costs and benefit alone, and NICE’s methods manuals explain when it is acceptable to recommend an intervention with a higher cost effectiveness estimate than £20,000 per QALY gained.
2. The NICE health technology evaluations manual gives specific reference to decisions made for technologies when the most plausible ICER is between £20,000 to £30,000 per QALY gained or over £30,000 per QALY gained.
3. Where a technology has previously received guidance from the Technology Appraisal Programme and is integrated into a guideline, decisions on continued adoption of these technologies in NHS clinical practice will specifically consider the acceptability of the technology as an effective use of NHS resources aligned with this range of maximum acceptable ICERs. As cost effectiveness is not the only basis for decisions, the Committee will consider technologies in relation to the range of maximum acceptable ICERs, and the influence of other factors on the decision to recommend a technology.

Guideline Recommendations

1. When a guideline committee considers one or more technology appraisals for integration in a guideline topic area, it may choose to make recommendations about preferred sequences or hierarchies based on an assessment of clinical effectiveness and cost-effectiveness. Whether options are presented as sequences or hierarchies will depend on how options are used to treat the condition in clinical practice and the marketing authorisation for the technologies.
2. Where there is evidence that the technology provides appropriate benefits and value for money, the guideline committee may make recommendations that expand use from the population covered by the technology appraisal. The committee may also make recommendations for narrower use of the technology. For example, use only for patients with a particular condition who meet specific clinical eligibility criteria, only for a specific subgroup of people, or that the treatment must be given by staff with certain training or in a particular care setting.
3. If the committee agree that for the population outlined in the original technology appraisal guidance, the technology is unlikely to be cost effective or (given full consideration of evidence) a good use of NHS resources, a recommendation against a product will be made and the technology appraisal guidance will be withdrawn.

Funding requirements

1. The funding requirement associated with a positive technology appraisal recommendation will remain unchanged whenever the technology is included in a guideline as a recommended option, even if that recommended use is narrower than the original technology appraisal guidance.
2. The funding requirement will no longer apply if the technology appraisal guidance is withdrawn.

Commercial engagement

1. There will be a single opportunity to review existing simple discount patient access schemes;
   1. In response during or after stakeholder consultation, and
   2. In response to the final draft recommendations post- stakeholder consultation
2. There will be an opportunity to review and potentially revise an existing, or engage in discussion about a new, Commercial Access Agreement in response to the final draft recommendations post stakeholder consultation where NHS England confirms that they are willing to engage in such discussions.
3. All commercial activities will be in line with the NHS Commercial Framework for New Medicines.

The validation process for draft guidelines

1. The validation process and finalising and publishing the guideline recommendations will follow the methods and processes set out in [developing NICE guidelines: the manual.](https://www.nice.org.uk/process/pmg20/chapter/introduction)

Appeals process

1. Where technology appraisal guidance is withdrawn following integration into a guideline, [consultees](https://www.nice.org.uk/Glossary?letter=C) outlined in the stakeholder list can appeal the guidance withdrawal and accompanying guideline recommendation, or the process followed using an amended technology appraisal appeal process (see paragraph 35).
2. The technology appraisal appeals process will only be amended to reflect the methods and processes used for integrating technology appraisals into a NICE guideline, and that the recommendations are made by a NICE guideline committee instead of a NICE appraisals committee.
3. Only [consultees](https://www.nice.org.uk/Glossary?letter=C) can lodge an appeal. Consultees will not be able to re-appeal any points from the original technology appraisal development process. Consultees will be outlined using the stakeholder list (or matrix) published as part of the original technology appraisal guidance development. During guideline development stakeholders will be able to request updates to the stakeholder list. NICE will approve updates where they reflect changes over time and are aligned with the current definitions of consultees outlined in [section 1.2.18 of the NICE health technology evaluations manual.](https://www.nice.org.uk/process/pmg36/chapter/involvement-and-participation#participants-in-the-evaluation-process)

Updates to this interim methods and process statement

1. Following consultation on the interim method and process statement and pilot topics, the statement will be reviewed and published. After completion of the pilot topics the final methods and processes will be included in NICE methods and process manuals.